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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,793	01/16/2004	Christopher A. Crawford	1027.P010USC1	8277

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EXAMINER	
SONNETT, KATHLEEN C	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,793	CRAWFORD, CHRISTOPHER A.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 21-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/16/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-11, drawn to a tunneling tool, classified in class 606, subclass 210.

   II. Claims 12-20, drawn to a method of forming a subdural pathway, classified in class 128, subclass 898.

   III. Claims 21-27, drawn to a neuromodulation therapy system, classified in class 600, subclass 554.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using such as the tunneling tool can be used to form a tunnel straight into tissue instead of a tunnel connecting two incisions.

3. Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination I has separate utility such as

the tunneling tool can be used in a number of procedures that do not involve a stimulation lead or generator. The tunneling tool can be used to form a tunnel in tissue for any surgery, such as an anastomosis procedure. See MPEP § 806.05(d).

4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process such as the stimulation lead may be positioned by a tunneling tool that does not form a pathway between a first and second incision.

5. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with R. Ross Viguet on 5/2/2006 a provisional election was made with traverse to prosecute the invention of the method of forming a subdural pathway, claims 12-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-11 and 21-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities: typographical error in line 2 of paragraph [0011] of the specification. The sentence reads, "the tube may remains in place within the tissue ".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claims 12, 16, 17, and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, III (U.S. 4,832,687) in view of Richmond (U.S. 4,509,516). Smith discloses a method of forming a subdural pathway between a first and second incision for an implantable line including the steps of inserting a tunneling tip (18) into a first incision and guiding the tunneling tool from the first to the second incision to form a subdural pathway, securing the line to the tunneling tool, and backing the tunneling tool out from the first incision along the subdural pathway to lay the implantable line along the pathway (col. 2 lines 15-31). Smith fails to disclose that the line is secured to the tunneling tool with a tapered slot proximate to the tunneling tip that pinches the line.

9. However, Richmond discloses that it is old and well known in the art to guide an implantable line through a pathway formed in tissue by securing the line to a tunneling tool by passing the line through a tapered slot (18) near the tunneling tip (col. 4 lines 41-8). The slot (18) is an elongated hole and is therefore tapered as you move from the center of the slot toward an end where the sides of the hole begin to curve. The tapered slot disclosed by Richmond is an equivalent means of connecting the implantable line to the tunneling tool as sliding the line over threads on the tunneling tool as disclosed by Smith. The slot may be formed in only a portion of the threaded region of the shaft so the cap (18 of Smith) may still be fit onto the device during the initial tunneling. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Smith to replace the friction fit with a tapered slot near the tunneling tip made obvious by Richmond as both mechanisms provide an equivalent means of attachment for the implantable line and tunneling tool.

10. Regarding claim 16, as seen in Fig. 4 of Smith, the first incision (32) is located near a terminal region and the second incision (36) is located near the treatment region. The terminal region is being considered the region around where the first incision is made. The treatment region is somewhere along the pathway and therefore, the second incision is proximate to the treatment region.

11. Regarding claim 17 and 18, the implantable line is a catheter (26) that is operable to deliver medication or drain the treatment region.

12. **Claims 19 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith and Richmond as applied to claim 16 above, and further in view of Ritz et al.

(U.S. 5,782,841). The modified device and method of Smith discloses the invention substantially as stated above, but fails to disclose the implantable line comprising a lead operable to deliver electrical signal to neuromodulate tissues from a signal generator and to electrodes proximate to the terminal region.

13. However, Ritz et al. discloses that it is old and well known to use tunneling tools for subcutaneous lead placement. Ritz et al. discloses a method of first passing a tunneling tool from one incision to another incision, connecting leads to the tunneling tool, and then placing the leads along the pathway as the tool is backed out of the first incision (col. 1 lines 56-67). These leads are tunneled between a signal generator and electrodes (col. 1 lines 16-20) in conjunction with the implant of pacemakers. The method disclosed by Smith for the implantation of a catheter follows similar steps of the method of implanting leads as disclosed by Ritz et al. The modified device of Smith has a tapered slot that is capable of engaging a variety of surgical instruments, including a lead. Therefore, it would have been obvious to one of ordinary skill in the art to use the modified device and method of Smith to implant electrical leads in order to gain the advantage of having a multi purpose tool that can be used for both catheter and lead placement during surgery.

14. Regarding claim 20, see col.1 lines 24-37 of Ritz et al.

15. **Claims 13 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith and Richmond as applied to claim 12 above, and further in view of Allen (U.S. 1,711,579). The modified device of Smith discloses the invention substantially as stated above, but fails to disclose that the tapered slot comprises a wide opening

located opposite of the tunneling tip and tapered sides that taper inwardly toward the tunneling tip, wherein the wide opening receives the implantable line and the tapered sides secure the line to the tunneling tool.

16. However, Allen discloses that it is old and well known in the art to use a tapered slot (Fig. 2, "3") to hold a tubular element, in this case surgical suture, in place. The slot comprises a wide opening located opposite of the tip of the needle and tapered sides that taper inwardly toward the tip. The shape of the slot performs the function of providing additional holding means for the strand as it is wedged into the wedge-shaped portion of the slot when it is used during surgery (col. 2 lines 79-86). Employing this shape in the modified device of Smith would allow the implantable line to be wedged into the narrower tip of the slot to provide a holding means. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Smith to include a tapered slot with a wider base and narrower tip in order to gain the advantage of a stronger holding means for keeping the implantable line attached to the tunneling tool during insertion.

17. Regarding claim 14, the handle (16) is a bent portion (20) of the shaft (12) (Smith, Fig. 4).

18. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, Richmond, and Allen as applied to claim 13 above, and further in view of McCarthy (U.S. 4,574,806). The modified device of Smith discloses the invention substantially as stated above, but fails to disclose a tube concentrically mounted about the shaft,

wherein the tube remains located along the subdural pathway to protect the implantable lead.

19. However, McCarthy discloses that it is old and well known to include a tube (14) that is concentrically mounted about a shaft (30) wherein the tube remains located along the subdural pathway during a tunneling procedure (Fig. 2, 4-7). The tunneling tool disclosed by McCarthy is inserted into a first incision and tunneled to a second incision, wherein the tube (14) remains in the tunnel while the cap (12) is removed from the shaft and a tissue graft is attached to the tip of the shaft. The graft is then pulled back through the subdural pathway. The tube protects the graft while it is pulled through the pathway (col. 2 lines 45-64 and col. 5 lines 64-67). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Smith to include a concentrically mounted tube that would remain located along the subdural pathway as made obvious by McCarthy in order to gain the advantage of protecting the implantable line and the tissue forming the tunnel from possible damage.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCS
5/4/2006

GLENN K. DAWSON
PRIMARY EXAMINER